

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 19 SEP 2005	
Applicant's or agent's file reference UCIVN-068PC	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US05/09527	International filing date (day/month/year) 23 March 2005 (23.03.2005)
Priority date (day/month/year) 23 March 2004 (23.03.2004)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/4015; C07D 233/42 and US Cl.: 514/392; 548/324.5	
Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Laura L. Stockton, Ph.D. Telephone No. 571/272-1600
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**WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report(Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-49 (all in-part)

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. Citations and explanations:

Claims 1-11, 16, 19-21, 23-36, 41, 44-46, 48 and 49 (all in-part) novelty under PCT Article 33(2) as being anticipated by:

- a) U.S. Patent 3,196,152 - see, for instance, Example XVI in column 6; or
- b) FR 1,516,714 - see, for instance, Example 20 on page 6, second column.

Each of the above prior art disclose at least one compound, in pharmaceutically acceptable carriers, that is used for a pharmaceutical purpose (i.e., psychopharmaceutics). Therefore, the instant invention lacks novelty.

Claims 1-13, 16, 17, 19-21, 23-38, 41, 42, 44-46, 48 and 49 (all in-part) lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent 3,196,152 and FR 1,516,714.

Each of U.S. Patent 3,196,152 (column 1; and especially Example XVI) and FR 1,516,714 (page 1; and especially Example 20) teach 2-imidazolidi-ones or thiones that are either structurally the same as or structurally similar to the instant claimed products. The difference between some of the products of the prior art and the products instantly claimed is that the instant claimed products are generically described in the prior art. The indiscriminate selection of "some" among "many" is obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., psychopharmaceutics). One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as a psychopharmaceutic. Therefore, the instant claimed invention lacks an inventive step.

Claims 14, 15, 18, 22, 39, 40, 43 and 47 (all in-part) meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the invention found in these claims.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 22 and 45-47 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): (1) a period is missing at the end of claims 22 and 45; (2) claim 46 is missing the claim number; and (3) the formula is missing in claim 47.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 12-15, 17, 18, 22, 37-40, 42, 43 and 47 (all in-part)

The opinion as to Novelty was negative (No) with respect to claims 1-11, 16, 19-21, 23-36, 41, 44-46, 48 and 49 (all in-part)

The opinion as to Inventive Step was positive (Yes) with respect to claims 14, 15, 18, 22, 39, 40, 43 and 47 (all in-part)

The opinion as to Inventive Step was negative (NO) with respect to claims 1-13, 16, 17, 19-21, 23-38, 41, 42, 44-46, 48 and 49 (all in-part)

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-49 (all in-part)

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE